

**REMARKS**

Now in the Application are Claims 3 and 25-31 of which Claim 3 is independent. Claims 1, 2, and 4-24 are withdrawn from further consideration. Applicant contends that the pending claims are patentable and in condition for allowance.

**CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)****A. Rejection of Claims 3 and 25-29 under 35 U.S.C. §103:**

Claims 3, 25, 26, 27, 28, and 29 stand rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,562,718 of Palermo, et al. (hereinafter “Palermo”), in view of U.S. Patent No. 1,557,417 of Cheney (hereinafter “Cheney”). Applicant respectfully traverses this rejection and contends that neither Palermo nor Cheney, alone or in combination, detracts from the patentability of these claims.

Claims 3 and 25-29 are directed to an apparatus for the manipulation of tissue. The claimed apparatus includes a control module and one or more conductor tools. The control module controls parameters of an electrical pulse suitable for innovating nerves in the tissue. The one or more conductor tools deliver the electrical pulse to the nerves. The control module is configured to enable the adjustment of the width of the electrical pulse at levels in the range of 33 µSecs to 132 µSecs and the pulse repetition frequency at levels below about 500 Hz. The control module is configured to enable the adjustment of the peak output voltage of the pulse in a range of between zero volts and about 130 volts. At least one conductor tool includes a frame of electrically conductive material having rotatably mounted thereon an electrically conductive roller and a handle of electrically insulting material. The roller being mounted in electrically conductive communication with the frame. The at least one conductor tool also includes means for electrically connecting the tool with the controlled electrical pulse.

A significant feature of the present invention is the capability of stimulating and detecting muscle recruitment at a micro level, thereby enabling more accurate diagnosis and more focus treatment of neuromuscular disorders. It has been discovered, that when a muscle contracts, at a macro level, it can be comprised at a micro recruitment level which is not detectable using conventional diagnostic methods. Normally, the muscle receptors detect the

contraction of the muscle and stimulate recruitment of other muscles in the group progressively. When a nerve is stimulated, if there has been an injury, pathology or a trauma, the recruitment pattern is often compromised. Generally, one full muscle recruitment is incurred; this presents itself in the patient as a cramp, followed by tension and pain. The presence or absence of these sensations can be used to evaluate the recruitment pattern for the tested muscle group. Hence, by providing the ability to stimulate muscle groups at a micro level, the apparatus of the present invention enables a clinician, such as a medical technician, nurse, nurse practitioner, doctor, and other like medical professionals to diagnose where a recruitment anomaly pattern exists. Once the anomaly is diagnosed, the apparatus can be used as a therapeutic tool to rehabilitate and re-educate the patients recruitment pattern.

The Palermo patent is directed to an electronic neuromuscular stimulation device operated by a computerized electronic control unit. The electronic control unit includes at least two output channels to which are connected to a corresponding set of electrode output cables. Each cable has attached a positive electrode and a negative electrode that are attached to selected areas of a patient's anatomy. The electronic neuromuscular simulation device of Palermo teaches the use of a select number of electrodes affixed to specific locations on a patient in order to accurately deliver controlled electrical pulses thereto.

The Cheney patent teaches a massage apparatus. The disclosed Cheney massage apparatus provides a brush and wire arrangement to electrify a roller assembly of the massage apparatus. The brush being selectively positionable so as to be in or out of contact with the roller of the disclosed massage apparatus. The wire appears to pass through the frame (A) of the massage apparatus to connect with an electrical source. The roller assembly of the Cheney massage apparatus is not in electrically conductive communication with the frame.

The Palermo reference in view of the Cheney reference does not detract from the patentability of the subject matter recited in Claims 3 and 25-29. The Cheney patent pre-dates the Palermo patent by almost seventy years, yet the Palermo patent makes no suggestion that the neuromuscular simulation system described therein could be used with a massage apparatus in order to produce a therapeutic result. In fact, the Palermo patent describes application of electrodes to a selected area of living tissue and that the electrodes are attached to a tissue. This

suggests that the positioning of electrodes and maintaining of the electrodes at a given position is crucial if the controlled electrical pulses are to be delivered in the appropriate manner to treat the damaged tissue.

Furthermore, the Cheney patent teaches that the rotary head of the electrode therapeutic massage device be carried by a frame is electrically isolated therefrom. *See*, lines 81-85 of Cheney. Moreover, the Cheney patent teaches a brush and wire arrangement, the brush being selectively positioned so as to be in or out of contact with the massage head. The brush and wire arrangement does not permit the accurate control of an electrical pulse and it's delivery to a roller assembly because of the tendency of the brush to wear over time and possibly oxidize over time. Hence, continuous electrical contact between the roller and frame is needed to provide accurate delivery. In contrast, Claims 3 and 25-29 of the instant application recite an apparatus for the manipulation of tissue that includes at least one conductor tool with a frame of electrically conductive material having rotatably mounted thereon an electrically conductive roller and a handle of electrically insulating material. The roller being mounted in electrically conductive communication with the frame. Neither the Palermo patent nor the Cheney patent, alone or in combination, teach or suggest a conductor tool that includes a frame of electrically conductive material having rotatably mounted thereon an electrically conductive roller, the roller being mounted in electrically conductive communication with the frame. The Palermo patent teaches electrodes affixed to a select location of the patient and the Cheney patent teaches a massage head electrically isolated from the frame. *See*, lines 80-85 of Cheney.

Moreover, the cited Palermo patent and the cited Cheney patent do not suggest the desirability of Applicant's claimed invention. Nowhere is there a motivation to combine the cited references. The statement in the Office Action that one having ordinary skill in the art at the time the invention was made would have modified the teachings of Palermo to include at least one conductor tool comprising a frame of electrically conductive roller and a handle of electrically insulating material, the roller being mounted in electrically conductive communication with the frame and means for electrically connecting the tool with a controlled electrical pulse, as taught by Cheney, as an alternate means of stimulation is merely conclusive. This statement is not sufficient by itself to establish a *prima facie* case of obviousness with which to reject Applicant's claimed invention. *See*, M.P.E.P. §2143.01. Specifically, the

Palermo patent does not explicitly or implicitly teach a movable means for delivering a therapeutic or diagnostic treatment, and in fact, teaches a fixed delivery means.

For at least these reasons, Applicant contends that the Palermo patent in view of the Cheney patent fails to establish a *prima facie* case of obviousness because, neither the Palermo patent nor the Cheney patent, alone or in combination fail to teach or suggest each and every element of the claims. Furthermore, there exists no suggestion or motivation to combine the references in the manner suggested by the Examiner and hence, there is no reasonable expectation of success found in the applied references.

Accordingly, Applicant respectfully request the Examiner to reconsider and withdraw the rejection of Claims 3 and 25-29 under 35 U.S.C. §103(a).

**B. Rejection of Claims 30 and 31 Under 35 U.S.C. §103(a):**

Claims 30 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Palermo in view of Cheney and further in view of U.S. Patent No. 4,846,181 of Miller, *et al.* (hereinafter “Miller”).

Claims 30 and 31 depend directly or indirectly from independent Claim 3 and therefore incorporate the patentable features of Claim 3. The further recitation in Claim 30 of a bath suitable for receiving and holding saline solution at a temperature between about 36°C and 42°C, provides a separate for the basis for patentability. Likewise, the further recitation in Claim 31, of a control panel for monitoring and/or controlling *inter alia* the temperature of the fluid contained therein, provides a separate further basis for patentability.

As discussed above, in relation to the rejection of Claim 3 under 35 U.S.C. §103(a), the Palermo patent and the Cheney patent, either alone or in combination, fail to teach or suggest each and every element of Claim 3. The Miller patent is cited for teaching a bath suitable for receiving and holding saline solution at a temperature between about 36°C and 42°C. The Miller patent teaches a soft tissue wound healing therapy utilizing pulsed electrical stimulation. Nevertheless, the Miller patent fails to bridge the factual deficiencies of the Palermo patent and the Cheney patent and therefore neither the Palermo patent, nor the Cheney patent, nor the

Miller patent detract from the patentability of the subject matter recited in Claims 30 and 31. The Miller patent merely teaches an electrode in a saline bath and does not teach or suggest heated saline solution or a control panel for monitoring and/or controlling inter alia the temperature of fluid contained therein. Likewise, neither the Palermo patent nor the Cheney patent teach or suggest such features.

Accordingly, neither the Palermo patent, nor the Cheney patent, nor the Miller patent, alone or in any combination, teach or suggest the subject matter recited in Claims 30 and 31. Accordingly, the Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 30 and 31 35 U.S.C. §103(a).

### CONCLUSION

In view of the remarks set forth above, Applicant contends that Claims 3 and 25-31 presently pending in this application, are patentable an in condition for allowance. If the Examiner deems there are any remaining issues, we invite the Examiner to call the undersigned at (617) 227-7400.

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